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EXAMINER

KISH, JAMES M

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PAPER NUMBER

3737

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/688,801	<b>Applicant(s)</b> SOLAR ET AL.	
	<b>Examiner</b> JAMES KISH	<b>Art Unit</b> 3737	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,8-16,18-43,46-70,76,77,81-86,88 and 90-108 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-25,52,65,66,76,77,101-103 and 106 is/are allowed.
- 6) ☒ Claim(s) 1,4,5,8-16,18-22,26-43,46-51,53-64,67-70,81-86,88,90-100,104,105 and 107 is/are rejected.
- 7) ☒ Claim(s) 108 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/5/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed February 3, 2009 have been fully considered but they are not persuasive.

Regarding Applicant's statement of a brief interview and request for a full interview to discuss all of the pending claims "if all of the claims are not found to be in condition for allowance." Contrary to the Applicant's assertion that only claim 1 and 68 were discussed, the Interview Summary dated January 16, 2009 states that claims 1, 68 and 98 and 101 were all discussed. Also, Leibinger, Vilsmeier, Franklin, Allen and Kraus were discussed. The Examiner notes that the interview was not cut short due to time constraints but because the Applicant had no further comments. The brief interview is deemed to have been an appropriate full length interview (which is a standard 30 minutes). The Examiner does not believe that an interview at this time will further prosecution and the request is, therefore, denied.

In response to pages 44 and 45 as stating and defining improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

At the bottom of page 45, the Applicant states "Particularly rejections based on combination of non-analogous art, such as a fiducial and a non-analogous bone stimulation system, should be withdrawn." Analogous art, as stated in MPEP 2141.01(a), "must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). Since the Applicant does not specifically cite any references, it can only be assumed the "bone stimulation system" is directed toward the Kraus reference. Based on Section 2141.01(a), Kraus is in fact analogous art in that it teaches subject matter which specifically teach how the systems and methods of both Allen and Vilsmeier may be combined into a single system/method. Therefore, Kraus is reasonably pertinent to the particular problem with which the inventor was concerned.

Also, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. *In re Nomiya*, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA) 1969. In the case of Vilsmeier (which the applicant consistently argues for teaching two prominences), one versed in the art would learn from this reference that a conical divot in any spherical marker, wherein the divot has an apex at the center of the marker, can

be used to localize the marker with image data with the use of a localizing instrument. One of skill in the art would be able to deduce that the two prominences are a feature in Vilsmeier that is not required for the use of the conical divot and localizing features, because "a person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 127 S. Ct. at 1742.

Claim 1

On page 46, the Applicant states, "Only Vilsmeier discloses a member that can be contacted at a center to identify a center of the member." The Examiner respectfully disagrees. Figure 11 of Leibinger clearly illustrates a member that can be contacted at a center such that it is capable of being used to identify a center of the member (see **28** of Figure 11 of Leibinger). This is just an example and should not be misconstrued as the Examiner stating that **only** Leibinger and Vilsmeier contains this subject matter.

On page 47, the Applicant argues that the Office failed to provide proper motivation between Leibinger and Vilsmeier to teach a single-piece fiducial marker. This is moot because "a single-piece" was only added with the current claim amendments. Previous claim 17 discussed this subject matter and was not rejected under Leibinger and Vilsmeier. Therefore, this argument is moot.

On page 47, the Applicant states "there is no real reason to combine Franklin and Vilsmeier. Though the Office notes that one skilled may wish to increase precision, Applicants submit that the combined art does not disclose how increased precision would be achieved or how the increased precision would render obvious the present claims." Franklin teaches image analysis or user determination based on image data to

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determine marker locations. Vilsmeier teaches "introducing... the tip of the pointer precisely into the tip of the funnel, which is the centerpoint of the ball." It is obvious this will provide better precision than a user clicking on a general area of image data. The methods by which increased precision would be achieved are taught in the Vilsmeier reference. The motivation and the body of the rejection teach how the present claims are obvious in view of these references.

Applicant's argument on the bottom of page 47 that Vilsmeier teaches away because of the two prominences is deemed moot in view of the rejections made in the previous Office Action. The manner in which Vilsmeier images the marker in its own system is of no relevance to the rejections.

At the top of page 48, the Applicant states, "Allen fails to disclose a fiducial mark or member that includes an imageable fiducial locator head and a conical receptacle defined by the imageable fiducial locator head." The Examiner notes that this rejection is under 35 U.S.C. 103(a). Therefore, it is improper for the Applicant to present arguments as if the references were used under 35 U.S.C. 102. Vilsmeier cures the deficiencies of Allen and the 35 U.S.C. 103(a) rejection is proper. Therefore, this argument is moot.

In the middle of page 48, the Applicant discusses claim 31 as being allowable based on claim 1 as allowable over Franklin in view of Vilsmeier. Franklin in combination with Vilsmeier was previously rebutted on page 3 of this Office Action. Therefore, claim 1 is not allowable over these two references. The addition of "a

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headband defining holes" is new to the claims and will be dealt with in the following rejections.

Based on the above, the arguments in the Remarks dated February 3, 2009 do not overcome the references previously used in the rejections of claim 1.

#### Claim 10

On page 49, the APpliant argues Franklin in view of Vilsmeier and Overaker. Franklin and Vilsmeier have already been discussed on page 3 of this Office Action. The Applicant then argues that Overaker does not disclose a hygroscopic material. The Examiner respectfully disagrees. Page 10, line 18 of the pending application's specification states, "Illustrative examples of solid plastics that can be made hygroscopic include, among other things, nylon and polyurethane." Column 5, lines 47-56 of Overaker states, "Suitable materials from which the fastener may be formed include biocompatible polymer selected from the group consisting of: ... polyurethanes."

#### Claim 11

Applicant's state, "The cited art (Leibinger and Vilsmeier) requires at least two members to provide for an imageable portion and a portion defining anything that can reasonably be understood to be a receptacle." If this is referring to the two prominences of Vilsmeier, this is moot as based on the response on page 4 of this Office Action. If this is referring to "a single-piece fiducial marker member," this is moot because that language is not incorporated in claim 11. Leibinger's Figure 11 illustrates a fiducial with an imageable fiducial locator head where the head also defines a *substantially* conical

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receptacle within the head. The teachings of Vilsmeier further define for a completely conical divot that would allow localization of the centroid of the fiducial head, thereby teaching the claim limitations (see the rejection of this claim on pages 3-4 of the Office Action dated November 3, 2008). The Examiner asserts that proper motivation was provided in the previous Office Action. See page 4 of the Action dated November 3, 2008.

Regarding the Applicant's arguments at the bottom of page 50, Merriam-Webster defines a "kerf" as "a slit or notch made by a saw or cutting torch." Figure 3 of Leibinger clearly illustrates a slit or notch down the center portion of **22**. Furthermore, a seat is located between **22** and **32** in Figure 3 of Leibinger. Slit **22** is left open and is operable to allow bone fragments to pass through them during operation. In other words, the slit being left open would in no way prevent bone fragments from passing into this space. Therefore, this reads on the added claim limitation.

#### Claim 22

Regarding the use of the word, "defined" as used in this claim (e.g., "wherein a passage is defined by the conical receptacle defined within the imageable fiducial locator head and through the shaft"), this term is non-descript. In what way does the conical receptacle "define" a passage?

The Applicant's arguments regarding Leibinger and Vilsmeier are rendered moot in view of the amended portion of the claims.



The Applicant argues that Franklin and Vilsmeier with either of Stednitz or Ferrante is improper (see the rejection of claims 15 and 16). The Examiner respectfully disagrees. Franklin in combination with Vilsmeier has already been discussed on page 4 of this Office Action. These references together teach the limitations except for the use of an anchor. By incorporating the self-tapping and bone cutting threading taught by Stednitz or Ferrante, the anchor is deemed unnecessary. This reduces the cost to produce the devices need for the fiducial system. This would be obvious to one of skill in the art when the invention was made. Therefore, this combination is proper.

Regarding Grafton and Leclair, these references teach laterally expandable members, however, the specific mechanics added with the current amendments read over these two references and are discussed in the rejections below.

#### Claim 23

Regarding a protective cap sized and shaped for protecting a fiducial marker – the underlined portion is non-descript and not further limiting. To illustrate the non-descript nature of the word “protecting,” a parent protects its child throughout the parent’s entire life. While one could make educated guesses at what is meant by this, it is unclear whether this means a physical protection from bruises or scrapes, mentally from trauma or sadness, financial protection, etc. “Sized and shaped” is non-descript in that the cloth or drape that is described in Vilsmeier is larger than the fiducial markers and is therefore sized and shaped to cover and, therefore, protect the marker. Furthermore, the term “for” implies intended use of the cap and the limitations following

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the "for" are therefore intended use and must only be capable of performing the function.

Based on the amendments which structurally limit the protective cap, the arguments regarding the previously cited art are rendered moot.

Claim 25

See above regarding "a protective cap sized and shaped for protecting the fiducial marker."

The Examiner notes that the amended portion is confusing in that one can not easily visualize the direction in which the cylindrical circumferential portion extends, and similarly, which direction the distal base flange extends.

Based on the amendments which structurally limit the protective cap, the arguments regarding the previously cited art are rendered moot.

Claim 26

Franklin in combination with Vilsmeier has already been addressed on page 4 of this Office Action. Gordon may a "cover for a rod implant and not a fiducial marker at all," but is still analogous art in that it is pertinent to the particular problem with which the inventor was concerned, i.e., providing a protective cover to a medical device that protrudes from the body. Proper motivation was provided at page 14 of the Office Action dated November 3, 2008. See Claim 23 for discussion on "a protective cap sized and shaped for protecting the fiducial marker." Gordon illustrates that the cap extends

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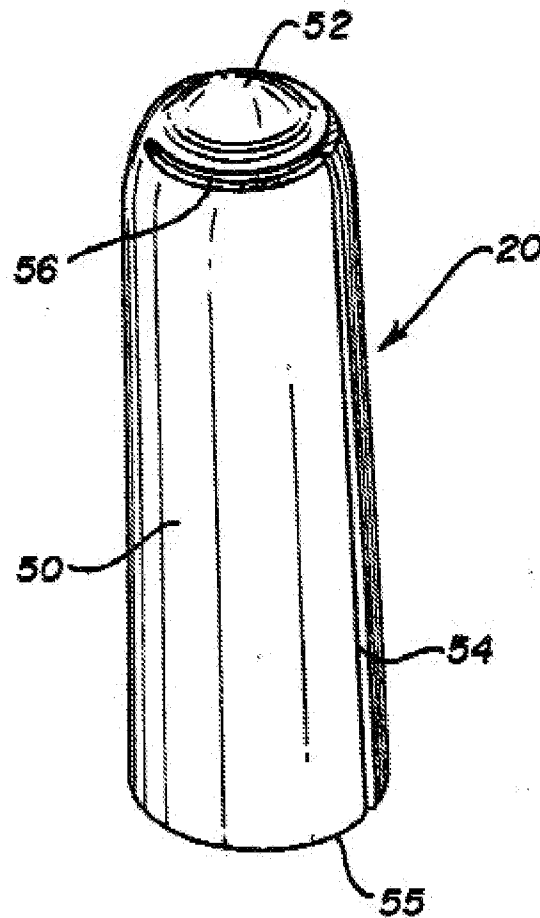
down to the patient's skin (Figure 11) and, therefore, would fit about the shaft of Franklin's fiducial marker.

For the following descriptions, see the excerpt of Figure 1 of Gordon on the following page.

Regarding claim 27, top slits **56** define a disk-like base portion. The center orifice is covered when top **52** is folded over (described in column 3, lines 18-32). **50** illustrates circumferential peripheral cylindrical sidewalls extending away from the disk-like base and substantially open at a proximal end of the... sidewall away from the disk-like base.

Regarding claims 28 and 29, **54** illustrates a radial slot which runs down the sidewall, but starts at the disk-like base portion.

Regarding claim 30, Figures 9 and 10 illustrate a disk-like cap sized and shaped to fit over a proximal portion of the sidewall (also see Figures 12 and 13).



Claim 32

The amendments to this claim have changed the scope. Furthermore, it is unclear where these amendments are described in the specification and what is meant that the bone screw shaft includes the driving portion which is accessible through the conical receptacle, used to drive the fiducial marker into a surface. It is unclear how the bone screw shaft is accessed through the conical receptacle. The best guess is Figures 22 and 23. However, these describe devices that are used to secure the marker in the bone, not drive the marker into the bone.

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Based on the amendments, the arguments surrounding this claim are moot due to the scope change.

#### Claim 36

Regarding “a slot extending through a side wall of the imageable fiducial locator head to be engaged by a driving instrument,” the Examiner notes that the marker head is spherical. A side wall on a spherical object is any side of the object. Allen’s and/or Kraus’ teaching of a slot (or notch or slit, etc.) for engagement with an allen wrench reads on this slot in that it extends from the surface, or side wall, or the spherical marker head. Kraus teaches a conical receptacle defined within the substantially spherical head by a straight wall sloping to an apex. Vilsmeier teaches that it is advantageous to have this sloped conical receptacle’s apex be located at a center of spherical marker head. In Kraus, the slot intersects with the conical receptacle. Therefore, the references still read on the amended portions of claim 36.

#### Claim 49

Regarding “a slot extending through a side wall of the imageable fiducial locator head to be engaged by a driving instrument,” see the comments under Claim 36.

The amendments defining a member using rotational means to expand the members reads over the prior art previously applied and changes the scope. See the following rejections.

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Claim 52

Regarding “a slot extending through a side wall of the imageable fiducial locator head to be engaged by a driving instrument,” see the comments under Claim 36.

See Claim 23 for discussion on “a protective cap sized and shaped for protecting the fiducial marker.”

The Examiner notes that the amended portion is confusing in that one cannot easily visualize the direction in which the cylindrical circumferential portion extends, and similarly, which direction the distal base flange extends.

Based on the amendments which structurally limit the protective cap, the arguments regarding the previously cited art are rendered moot.

Claim 53

Allen, Vilsmeier and Kraus were previously discussed under Claim 36.

See Claim 23 for discussion on “a protective cap sized and shaped for protecting the fiducial marker.”

Gordon may a “cover for a rod implant and not a fiducial marker at all,” but is still analogous art in that it is pertinent to the particular problem with which the inventor was concerned, i.e., providing a protective cover to a medical device that protrudes from the body.

Claim 59

Figure 11 of Leibinger clearly illustrates a member that can be contacted at a center such that it is capable of being used to identify a center of the member (see **28** of Figure 11 of Leibinger). This is just an example and should not be misconstrued as the Examiner stating that **only** Leibinger and Vilsmeier contains this subject matter. Vilsmeier teaches that conical divot having straight walls can be used to locate the center of that divot with a positioning instrument. It would be obvious to combining this teaching of Vilsmeier with the Leibinger device, as it has been described in the previous Office Action.

The Applicant's assertion that Allen's markers are implanted does not render them useless against the current claims. Figure 2b of Allen clearly shows the markers on an external surface of the patient's head. The bone screw portion is "implanted" into the bone of the patient, yet still residing external to the patient. The teachings of Vilsmeier as described in the previous paragraph, when combined with Allen, teach the claimed subject matter. This combination is described in the previous Office Action.

#### Claim 64

The amendments directed toward an engaging member that utilizes rotational motion to expand lateral portions changes the scope of this claim. Based on this, the arguments are moot.

#### Claim 65

The amendments directed toward “passing a shaft extending from the imageable fiducial locator head through a peripheral slot and a radial slot in the protective collar” changes the scope of this claim. Based on this, the arguments are moot.

Claim 68

Regarding the amendments directed toward a first member that is later removed and a second member that is not removed, the Examiner cites Figures 9A-C. The washer **66** is a first member and the cannula **62** is a second member. These figures illustrate that the first member remains even after the second member is removed. The first member continues to protect the shaft of the bone screw device after implantation. Winters is analogous art in that it is pertinent to the particular problem with which the inventor was concerned.

Claim 76

The amendments directed toward a protective cap having an inner member and an outer member with height adjustment changes the scope of this claim. Based on this, the arguments are moot.

Claim 81

The Examiner disagrees with the Applicant that Leibinger and Vilsmeier fail to teach the claimed subject matter of a fiducial marker including a head that both is imageable and defines a receptacle. The rejection is based on 35 U.S.C. 103.



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However, the Applicant appears to continuously argue the references independent of one another.

As previously discussed, the Examiner believes that Allen in view of Vilsmeier and Kraus also teach this subject matter. Similarly, Franklin and Vilsmeier teaches this claimed subject matter.

Regarding the word "imageable:" if the "plug" is capable of being used in an imaging system and does not destroy the system, it is considered as able to be used with an imaging system and is, therefore, imageable. Therefore, the plug (or cap) of Leibinger is imageable.

Furthermore, if the plug is metal, it is imageable within an x-ray system, but not an MRI system. If the plug is visible with the naked eye, it is imageable with a camera.

Based on the above arguments, the references still read on the claim 81.

#### Claim 88

The amendments directed toward fins located on the imageable plug, as well as the plug itself, have changed the scope of this claim. Based on this, the arguments are moot.

#### Claim 91

Merriam-Webster defines *unitary* as "of or relating to a unit." Furthermore, Merriam-Webster defines a *unit* as "**3 c** : a piece of complex of apparatus serving to perform one particular function." Therefore, Leibinger having multiple pieces that each

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work together to achieve the many portions of claim 91 still reads on the claim as being unitary.

The cap **40** of Leibinger (as illustrated in Figure 11) is very clearly fit within the receptacle. Likewise, while being named a "cap," it is a plug and it is imageable.

Further regarding the plug, see the comments under Claim 81.

Regarding claim 93, the amendment has changed the scope of the claim. See the following rejections regarding this change of scope.

#### Claim 94

The amendments directed toward an engaging member that utilizes rotational motion to expand lateral portions changes the scope of this claim. Based on this, the arguments are moot.

#### Claim 98

Regarding the amendments directed toward a first member that is later removed and a second member that is not removed, the Examiner cites Figures 9A-C. The washer **66** is a first member and the cannula **62** is a second member. These figures illustrate that the first member remains even after the second member is removed. The first member continues to protect the shaft of the bone screw device after implantation. Winters is analogous art in that it is pertinent to the particular problem with which the inventor was concerned.

Claim 101

The amendments directed toward the guide collar having an inner member and an outer member, and wherein the inner member is removed laterally changes the scope of this claim. Based on this, the arguments are moot.

***Claim Objections***

Claims 31, 90 and 108 are objected to because of the following informalities:

Claim 31 is objected to because it is unclear how a headband defines holes. The term "defines" is non-descriptive and it is recommended that this language be avoided for not providing any clear limitation. This claim is currently being broadly interpreted in that the headband is elastic and circular. The patient's head fits within the center *hole* of the headband and it is used to hold markers. By preventing these markers from falling off the patient, they are protected from the impact of hitting the ground.

Therefore, Franck still reads on this claim.

Claims 90 and 108 are objected to because these claims disclose a "cover." However, the Examiner believes this "cover" to be the same portion of the apparatus claimed as a "protective cap" in other claims. The Applicant is requested to provide consistency amongst terms used in the claims.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-5, 8-9, 11-12, 19-20, 59-63, 81-86, 91-92 and 104-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger et al.** (US Patent No. 5,394,457) – herein referred to as Leibinger - in view of **Vilsmeier** (US Patent No. 6,351,659), further in view of **Allen**. Leibinger discloses a fiducial marker device as illustrated in Figure 13. The device has a spherical top portion with a shaft that extends downward. At the bottom of the device is a screw that is to be driven into a tissue to be secured. As illustrated in Figure 3, there is a seat between **32** and **22**, as well as a kerf. As illustrated in Figure 11, a plug may be removed to access the center of the device. When the plug is removed, a substantially conical divot remains. The walls of this divot

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are substantially continuous toward an apex. When the plug is replaced, **42** illustrated a slot for engagement of a screwdriver (column 5, lines 6-8). The substance that is to be placed in the center of **28** may be used to image in multiple imaging modalities.

Figures 1-3 illustrate a laterally expandable distal end. The plug **40** may be considered a cap and protects the marking substance that is inside the head portion.

However, there is no teaching in Leibinger for any other purpose for the hollow center except for placement of an imagable marker. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. The system has spherical markers provided with a reflective coating (column 4, lines 24-28). Furthermore, a “funnel configuration” is used to access precisely the center point of the landmark with a point. Due to the landmark’s funnel configuration they can be localized even after they are covered by a cloth. See column 7, lines 20-47, as well as Figure 8. Also, column 12, lines 1-11 teach the ease of sterilization of the markers. Once the markers have been sterilized they would obviously have a coating of sterilizing agent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the hollowed center of Leibinger in a similar fashion to that of Vilsmeier in order to allow a surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47).

However, no portion of a bone screw shaft that is a single-piece of the fiducial head and that is configured to be directly secured to a bone is taught in Leibinger. Allen discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has a head which is spherical and a second portion 14

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that is to be secured to the bone (column 5, lines 1-19). This first portion is preferably hollow and can be filled with a gel having various desired dopants, depending on the imaging system (column 7, lines 32-39). Figure 1a shows an embodiment wherein second portion 14 is not threaded and would need to be driven into the bone by a means other than screwing. Allen discloses registering an external coordinate system B of a robotic arm with an internal coordinate system A. This is accomplished by touching the tip of the robotic arm on the fiducial implant (column 14, lines 28-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the fiducial system of Leibinger a single-piece device to minimize the possibility of lost parts, thereby making the remains parts useless and therefore, saving money and materials.

Claims 22, 49 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger** in view of **Vilsmeier**, and further in view of any one of **Barmlet et al.** (US Patent Pub. No. 2001/0000186) - herein referred to as Barmlet - and **Levisman** (US Patent Pub. No. 2002/0028423) and **Lazarof** (US Patent Pub. No. 2005/0042574). Leibinger discloses a fiducial marker device as illustrated in Figure 13. The device has a spherical top portion with a shaft that extends downward. At the bottom of the device is a screw that is to be driven into a tissue to be secured. As illustrated in Figure 3, there is a seat between **32** and **22**, as well as a kerf. As illustrated in Figure 11, a plug may be removed to access the center of the device. When the plug is removed, a substantially conical divot remains. The walls of this divot are substantially continuous

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toward an apex. When the plug is replaced, **42** illustrated a slot for engagement of a screwdriver (column 5, lines 6-8). The substance that is to be placed in the center of **28** may be used to image in multiple imaging modalities. Figures 1-3 illustrate a laterally expandable distal end. The plug **40** may be considered a cap and protects the marking substance that is inside the head portion. However, there is no teaching in Leibinger for any other purpose for the hollow center except for placement of an imageable marker. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. The system has spherical markers provided with a reflective coating (column 4, lines 24-28). Furthermore, a "funnel configuration" is used to access precisely the center point of the landmark with a point. Due to the landmark's funnel configuration they can be localized even after they are covered by a cloth. See column 7, lines 20-47, as well as Figure 8. Also, column 12, lines 1-11 teach the ease of sterilization of the markers. Once the markers have been sterilized they would obviously have a coating of sterilizing agent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the hollowed center of Leibinger in a similar fashion to that of Vilsmeier in order to allow a surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47).

However, neither Leibinger nor Vilsmeier teach the expansion member being activated with a rotation mechanism as taught by these claims.

Bramlet teaches a surgical bone fastener assembly. As illustrated in Figure 5 and 6, a threaded portion **134** at a proximal end is rotated to cause portions **60** to expand outward from the screw-like base portion.

Levisman teaches a bone implant for fixing a prosthetic to bone (see Figures 12 and 13). Rotation of the inner threaded portion pulls **33** upward, simultaneously causing **44** to expand outward.

Lazarof teaches an implant having an expandable skirt... for anchoring the implant within the bone of the patient (see Abstract). See, at least, Figures 2 and 3.

Therefore, it was obvious to one of ordinary skill in the art at the time the invention was made to utilize a hollow conduit in the center of screw-like devices that carries a rotatable driveshaft to cause expandable members at a distal end of the screw-like device to anchor the device into bone. It would be obvious to one of ordinary skill in the art to utilize these mechanics with a fiducial marker, or any device that is intended to be secured to a bone, as taught by the references.

Claims 32-35, 40-42, 45-48, 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger** in view of **Vilsmeier** and further in view of **Allen**, and further in view of any one of **Barmlet**, **Levisman**, and **Lazarof**. Leibinger in view of Vilsmeier is described above in the rejection of claim 1. However, no portion of a bone screw shaft that is a single-piece of the fiducial head and that is configured to be directly secured to a bone is taught in Leibinger. Allen discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has a head which is spherical and a second portion 14 that is to be secured to the bone (column 5, lines 1-19). This first portion is preferably hollow and can be filled with a gel having various desired dopants, depending on the imaging system (column 7, lines 32-



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39). Figure 1a shows an embodiment wherein second portion 14 is not threaded and would need to be driven into the bone by a means other than screwing. Allen discloses registering an external coordinate system B of a robotic arm with an internal coordinate system A. This is accomplished by touching the tip of the robotic arm on the fiducial implant (column 14, lines 28-53).

However, none of Leibinger, Vilsmeier nor Allen teach a driving portion accessible through a conduit through the head as taught by these claims.

Bramlet teaches a surgical bone fastener assembly. As illustrated in Figure 5 and 6, a threaded portion **134** at a proximal end is rotated to cause portions **60** to expand outward from the screw-like base portion.

Levisman teaches a bone implant for fixing a prosthetic to bone (see Figures 12 and 13). Rotation of the inner threaded portion pulls **33** upward, simultaneously causing **44** to expand outward into the surrounding surfaces.

Lazarof teaches an implant having an expandable skirt... for anchoring the implant within the bone of the patient (see Abstract). See, at least, Figures 2 and 3.

Therefore, it was obvious to one of ordinary skill in the art at the time the invention was made to utilize a hollow conduit in the center of screw-like devices that carries a rotatable driveshaft to cause expandable members at a distal end of the screw-like device to anchor the device into bone. It would be obvious to one of ordinary skill in the art to utilize these mechanics with a fiducial marker, or any device that is intended to be secured to a bone, as taught by the references.

Claims 68-70 and 98-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger** in view of **Vilsmeier** and **Allen**, and further in view of **Winters** (US Patent No. 6,464,706). Leibinger in view of Vilsmeier and Allen is described above in the rejection of claim 32. However, none of these references teach a guide collar that as described in the above claims. Winters teaches a system and associated methods for affixing soft tissue to bone. This is accomplished by inserting bone screws using a guide collar, as illustrated in Figures 7-12C. Figure 12A illustrates using the guide collar to insert the bone screw. The guide collar is still in place in Figure 12B. Upon withdrawal of the screw as shown in 12C, the guide collar may be laterally removed. Figures 9A-C illustrates an embodiment in which the guide collar may be removed axially. Furthermore, Winters illustrates that a hole is drilled before insertion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a collar, such as that taught by Winters, in the insertion of a screw that is to be fixed to a bone, such as the marker of Leibinger in combination with Vilsmeier and Allen, in order to accurately insert the marker.

Regarding "leaving the guide collar about the fiducial marker during a time period in which the patient is to be protected against a mechanical impact to the fiducial marker," this may be interpreted as keeping the guide around the marker while it is being driven into the patient or even a split second afterward and therefore, Winters reads on these limitations.

Claims 37-39 rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger** in view of **Vilsmeier, Allen** and any one of **Bramlet, Levisman, Lazarof** as applied to claim 32 above, and further in view of **McCrory** et al. (US Patent No. 6,333,971). **Leibinger** in view of **Vilsmeier** and **Allen** is described above. However, these bone screw portions do not provide an unthreaded portion. **McCrory** provides a base portion of an imageable fiducial marker assembly has having both a threaded portion and an unthreaded portion. The threaded portion **32**, as illustrated in Figure 2A and 2B, has a small maximum diameter than that of the unthreaded portion, providing for a depth stop. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a narrower threaded portion to separate the fiducial marker from the surface of the patient's skull/bone.

Claim 43 rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger** in view of **Vilsmeier, Allen** and further in view of any one of **Barmlet, Levisman, and Lazarof** as applied to claim 32 above, and further in view of either one of **Stednitz** et al. (US Patent No. 5,098,435) and **Ferrante** et al. (US Patent No. 6,565,573). **Leibinger** in view of **Vilsmeier** and **Allen** is described above in the rejection of claim 32. However, neither of these references discuss providing a self-tapping or bone cutting edge for the screw.

**Stednitz** et al. teaches a bone stabilizing system including a pin with an elongate solid shaft having one or more drilling teeth and self-tapping threads. A flute, best illustrated in Figure 6, provides for a cutting edge.

Ferrante et al. teaches an orthopedic screw that is preferably a self-tapping screw. As illustrated in Figures 1 and 2, flutes are created at the tip of the screw. Threads **40** of the screw cut into the bone.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize bone cutting and self-tapping threading on the screw portion Leibinger and Allen's fiducial marker in order to remove the need of providing an anchor. Since the anchor is invasively placed in the patient's skull already, this removes that need and lowers the cost for the device.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Leibinger** in view of **Vilsmeier**, **Allen** and any one of **Bramlet**, **Levisman**, **Lazarof** as applied to claim 32 above, and further in view of **Franck** et al. (US Patent No. 6,273,896). Leibinger in view of Vilsmeier and Allen is described above in the rejection of claim 32. However, none of these references clearly teaches a headband. Franck teaches as an alternative to implanting markers to instead use an elastic headband in which to place the markers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a headband to place over the head of the bone screw/fiducials of Leibinger, Vilsmeier and Allen in order provide an alternative method of placing the markers that is less invasive for the patient..

Claims 1, 5, 8-9, 12-16, 19-21, 59-61, 67 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier**. Allen discloses a

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fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has a head which is spherical and a second portion 14 that is to be secured to the bone (column 5, lines 1-19). This first portion is preferably hollow and can be filled with a gel having various desired dopants, depending on the imaging system (column 7, lines 32-39). Figure 1a shows an embodiment wherein second portion 14 is not threaded and would need to be driven into the bone by a means other than screwing. A trocar, or guide, is placed at the anchoring site and the marker is placed within the trocar, thereby providing a guide collar about the marker (column 8, lines 1-9). Allen discloses registering an external coordinate system B of a robotic arm with an internal coordinate system A. This is accomplished by touching the tip of the robotic arm on the fiducial implant (column 14, lines 28-53). While Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. The system has spherical markers provided with a reflective coating (column 4, lines 24-28).

Furthermore, a "funnel configuration" is used to access precisely the center point of the landmark with a point. Due to the landmark's funnel configuration they can be localized even after they are covered by a cloth. See column 7, lines 20-47, as well as Figure 8. Also, column 12, lines 1-11 teach the ease of sterilization of the markers. Once the markers have been sterilized they would obviously have a coating of sterilizing agent. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a funnel configuration, as taught by Vilsmeier, in the fiducial

system of Allen because Allen states that it is very important to locate the exact center of the marker (column 6, lines 61-68). Vilsmeier states that the funnel configuration allows the surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47).

Claims 1, 5, 8-9, 13-14, 18-19 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Franklin** et al. (US Patent No. 6,327,491) – herein referred to as Franklin - in view of **Vilsmeier**. Franklin discloses a surgical fixture formed by scanning a patient. In determining specific points on the patient's surface, fiducial markers and bone anchors are used as illustrated in Figure 1B. The screw portion is secured to an anchor, which is in turn secured to a bone. Column 4, lines 40-49 discusses a method in which the operator locates the positions of the scanning markers in the image space. As a functional equivalent to this approach, Vilsmeier teaches a reflector referencing system in which a pointer known to the system is placed in a conical divot located in the spherical head of a fiducial, as depicted in Figure 8 (column 14, lines 2-36). One advantage is that when the markers are covered with a cloth that is sized and shaped to fit over the marker heads, the conical divot is still accessible for localization. Vilsmeier also states that the shape, size and material selection for the markers is chosen to more accurately determine their position. The system has spherical markers provided with a reflective coating (column 4, lines 24-28). The reflective coating will provide a different imaging contrast with respect to optical imaging between the head and the shaft. It would have been obvious to one having ordinary

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skill in the art at the time the invention was made to utilize the method taught by Vilsmeier as a function equivalent to the localization method of Franklin to provide increased precision in the determination of the marker locations within the imaged space, and also to provide a system that is able to identify each of the landmarks within seconds (column 14, line 29).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Franklin** in view of **Vilsmeier** and further in view of **Overaker** et al. (US Patent No. 6,241,732). Franklin in view of Vilsmeier is described above in the rejection of claim 1. However, neither of these references teaches a hygroscopic solid material. Overaker discloses a bioabsorbable rivet and pin fastening device that may be used for attachment of a fixation plate to bone (see Abstract). Additionally, radio-opaque markers may be added to the rivet or pin to allow imaging of the rivet and pin fastener after implantation (column 7, lines 50-52). It would have been obvious to one of ordinary skill in the art to construct the marker of Franklin in combination with Vilsmeier out of the absorbable material of Overaker because Overaker already teaches the use of the material in fiducial marker situations and would increase the utility of Franklin's marker by allowing multi-modal imaging via the contribution of liquids within the material of the marker itself (see column 7, lines 1-13 and column 7, lines 50-52).

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Franklin** in view of **Vilsmeier** as applied to claim 1 above, and further in view of

either one of **Stednitz** et al. (US Patent No. 5,098,435) and **Ferrante** et al. (US Patent No. 6,565,573). Franklin in view of Vilsmeier is described above in the rejection of claim 1. However, neither of these references discuss providing a self-tapping or bone cutting edge for the screw.

Stednitz et al. teaches a bone stabilizing system including a pin with an elongate solid shaft having one or more drilling teeth and self-tapping threads. A flute, best illustrated in Figure 6, provides for a cutting edge.

Ferrante et al. teaches an orthopedic screw that is preferably a self-tapping screw. As illustrated in Figures 1 and 2, flutes are created at the tip of the screw. Threads **40** of the screw cut into the bone.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize bone cutting and self-tapping threading on the screw portion Franklin's fiducial marker in order to remove the need of providing an anchor. Since the anchor is invasively placed in the patient's skull already, this removes that need and lowers the cost for the device.

Claims 22, 64, 81-82, 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Franklin** in view of **Vilsmeier** and either one of **Stednitz** et al. and **Ferrante** et al., and further in view of any one of **Bramlet**, **Levisman**, **Lazarof**. Franklin in combination with Vilsmeier and either one of Stednitz et al. and Ferrante et al. is described above in the rejection of claims 15 and 16. In combination, these references teach a spherical fiducial marker with a conical divot for localization that is capable of



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secured to a bone without an anchor. However, none of these references teach an expandable distal tip of the shaft based on a rotating driveshaft.

Bramlet teaches a surgical bone fastener assembly. As illustrated in Figure 5 and 6, a threaded portion **134** at a proximal end is rotated to cause portions **60** to expand outward from the screw-like base portion.

Levisman teaches a bone implant for fixing a prosthetic to bone (see Figures 12 and 13). Rotation of the inner threaded portion pulls **33** upward, simultaneously causing **44** to expand outward.

Lazarof teaches an implant having an expandable skirt... for anchoring the implant within the bone of the patient (see Abstract). See, at least, Figures 2 and 3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Franklin in combination with the aforementioned references with an expandable distal end in order to properly secure the device into the bone.

Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Franklin** in view of **Vilsmeier**, and further in view of **Gordon** (US Patent No. 5,300,075). Franklin in combination with Vilsmeier is described above in the rejection of claim 1. In combination, these references teach a spherical fiducial marker with a conical divot for localization and methods of its use. However, none of these references teach a protective cap. Gordon teaches a cover for orthopedic devices that protrude from a patient's body (see Figure 11). The external housing (see Figures 9-10), which

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has a disk-like cap and is sized and shaped to fit over a proximal portion of the sidewalls shown in Figures 2-6, has smooth surfaces to avoid and minimize any trauma to surrounding body tissue (see Abstract). Figure 8 illustrates how the proximal end of the medical device is engaged by the cover. Figure 10 illustrates a cover that incorporates a disc-like base and circumferential peripheral cylindrical sidewalls. In Figures 2-6, a slot is shown that extends from the orifice and continues upward, finally circling outward where the sidewall meets the top. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a cover, as taught by Gordon, to a protruding medical device, such as the marker taught by Franklin, in order to avoid and minimize any trauma to surrounding body tissue (see Abstract) if the device is impacted by an external force.

Regarding claim 26, the protective cap described by Gordon covers the entirety of the medical device that is external to the patient surface, thereby including the shaft.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Franklin** in view of **Vilsmeier** as applied above to claim 1, and further in view of **Franck** et al. (US Patent No. 6,273,896). Franklin in combination with Vilsmeier is described above in the rejection of claim 1. However, none of these references clearly teaches a headband. Franck teaches as an alternative to implanting markers to instead use an elastic headband in which to place the markers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a headband

to place over the head of the bone screw/fiducials of Franklin and Vilsmeier in order provide an alternative method of placing the markers that is less invasive for the patient.

Claims 36 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier**, and further in view of **Kraus**, still further in view of either one of **Stednitz** et al. and **Ferrante** et al. Allen discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has at least a portion, which is spherical and defines a surface for cooperating with a tool for securing the second portion 14 to the bone (column 5, lines 1-19). Preferably, the anchor should be screwed into the bone, rather than driven with an impact tool to lessen the chance of fracturing the bone (column 7, lines 40-52). Where anchor is a screw, preferably an indentation in the shape of a polygon recess to receive an allen wrench is located in marker 12. The use of an allen wrench is due to the increased symmetrical integrity provided over the use of the cross shaped receptor site for a Phillips screw driver or a single groove receptor site for a standard screw driver (column 7, lines 53-61). However, if this symmetry was not important, it would be obvious to use one of these other screwdriver shapes. While Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. A "funnel configuration" is used to access precisely the center point of the landmark with a point. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a

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funnel configuration, as taught by Vilsmeier, in the fiducial system of Allen because Allen states that it is very important to locate the exact center of the marker (column 6, lines 61-68). Vilsmeier states that the funnel configuration allows the surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47).

As a teaching reference, Kraus teaches a bone screw with a substantially spherical head portion and a bone screw shaft. The head is provided with an inlet for engagement with an allen wrench type screwdriver. At the base of the inlet is provided a conical receptacle that provides a point located at the center of the circular head portion when viewed in the axial direction. Kraus teaches a apparatus that incorporates the structural limitations necessary to combine Allen with Vilsmeier. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use Kraus as a teaching reference to incorporate the center point localization of a spherical marker head, as taught by Vilsmeier, while also allowing an allen wrench to fix the screw into the bone, as taught by Allen.

However, none of these references teach a threaded portion having a quarter cylindrical cutout.

Stednitz et al. teaches a bone stabilizing system including a pin with an elongate solid shaft having one or more drilling teeth and self-tapping threads. A flute, best illustrated in Figure 6.

Ferrante et al. teaches an orthopedic screw that is preferably a self-tapping screw. As illustrated in Figures 1 and 2, flutes are created at the tip of the screw.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a cutout in the threading on the screw portion, as taught by Stednitz et al. and Ferrante et al., with the system of in order to provide a cutting edge to the screw while simultaneously allowing debris to clear.

Regarding claims 88, Allen teaches that “a sphere is the ideal shape for a marker with respect to symmetrical integrity since the image of any plane of the sphere is always a circle (column 7, lines 3-6).” Therefore, if the imageable plug did not fill plug all of the space that is absent due to a divot, slots, etc., the marker would not be spherical and would not possess the ideal symmetry. Therefore, it would be obvious to one of skill in the art to utilize a plug that created the ideal shape, i.e., a sphere.

Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier**, and further in view of **Kraus**, still further in view of either one of **Stednitz** et al. and **Ferrante** et al. as applied to claim 88 above, and further in view of **Gordon**. Allen in combination with the aforementioned references is previously described. However, none of these references teach a cover. Gordon teaches a cover for orthopedic devices that protrude from a patient's body (see Figure 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a cover, as taught by Gordon, to a protruding medical device, such as the marker taught by Franklin, in order to avoid and minimize any trauma to surrounding body tissue (see Abstract) if the device is impacted by an external force.

Claims 49, 64, 81-85, 94-97 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier**, and further in view of **Kraus**, still further in view of any one of **Bramlet**, **Levisman**, **Lazarof**. Allen discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has at least a portion, which is spherical and defines a surface for cooperating with a tool for securing the second portion 14 to the bone (column 5, lines 1-19). Preferably, the anchor should be screwed into the bone, rather than driven with an impact tool to lessen the chance of fracturing the bone (column 7, lines 40-52). Where anchor is a screw, preferably an indentation in the shape of a polygon recess to receive an allen wrench is located in marker 12. The use of an allen wrench is due to the increased symmetrical integrity provided over the use of the cross shaped receptor site for a Phillips screw driver or a single groove receptor site for a standard screw driver (column 7, lines 53-61). However, if this symmetry was not important, it would be obvious to use one of these other screwdriver shapes. While Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. A "funnel configuration" is used to access precisely the center point of the landmark with a point. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a funnel configuration, as taught by Vilsmeier, in the fiducial system of Allen because Allen states that it is very important to locate the exact center of the marker (column 6, lines 61-68). Vilsmeier states that the funnel configuration allows the

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surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47).

As a teaching reference, Kraus teaches a bone screw with a substantially spherical head portion and a bone screw shaft. The head is provided with an inlet for engagement with an allen wrench type screwdriver. At the base of the inlet is provided a conical receptacle that provides a point located at the center of the circular head portion when viewed in the axial direction. Kraus teaches a apparatus that incorporates the structural limitations necessary to combine Allen with Vilsmeier. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use Kraus as a teaching reference to incorporate the center point localization of a spherical marker head, as taught by Vilsmeier, while also allowing an allen wrench to fix the screw into the bone, as taught by Allen. Furthermore, Kraus teaches a plug that will protect the insides of the divot.

However, none of these references teach an expandable distal tip of the shaft based on a rotating driveshaft.

Bramlet teaches a surgical bone fastener assembly. As illustrated in Figure 5 and 6, a threaded portion **134** at a proximal end is rotated to cause portions **60** to expand outward from the screw-like base portion.

Levisman teaches a bone implant for fixing a prosthetic to bone (see Figures 12 and 13). Rotation of the inner threaded portion pulls **33** upward, simultaneously causing **44** to expand outward.

Lazarof teaches an implant having an expandable skirt... for anchoring the implant within the bone of the patient (see Abstract). See, at least, Figures 2 and 3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Allen in combination with the aforementioned references with an expandable distal end in order to properly secure the device into the bone.

Regarding claims 95-97, Vilsmeier teaches a cover may be placed over the markers while localization is still possible. Kraus teaches a cap that may be placed into a divot of a bone screw.

Regarding claim 107, Allen teaches that "a sphere is the ideal shape for a marker with respect to symmetrical integrity since the image of any plane of the sphere is always a circle (column 7, lines 3-6)." Therefore, if the imageable plug did not fill plug all of the space that is absent due to a divot, slots, etc., the marker would not be spherical and would not possess the ideal symmetry. Therefore, it would be obvious to one of skill in the art to utilize a plug that created the ideal shape, i.e., a sphere.

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier**, **Kraus**, and any one of **Bramlet**, **Levisman**, **Lazarof** as applied to claim 81 above, and further in view of **Overaker**. Allen in combination with Vilsmeier, Kraus, and any one of Bramlet, Levisman, Lazarof is described above in the rejection of claim 81. However, none of these references teaches a hygroscopic solid material. Overaker discloses a bioabsorbable rivet and pin fastening device that may be used for



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attachment of a fixation plate to bone (see Abstract). Additionally, radio-opaque markers may be added to the rivet or pin to allow imaging of the rivet and pin fastener after implantation (column 7, lines 50-52). It would have been obvious to one of ordinary skill in the art to construct the marker of Franklin in combination with Vilsmeier out of the absorbable material of Overaker because Overaker already teaches the use of the material in fiducial marker situations and would increase the utility of Allen's marker by allowing multi-modal imaging via the contribution of liquids within the material of the marker itself (see column 7, lines 1-13 and column 7, lines 50-52).

Claims 53-57, 76-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier**, and further in view of **Kraus**, still further in view of **Gordon**. Allen discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has at least a portion, which is spherical and defines a surface for cooperating with a tool for securing the second portion 14 to the bone (column 5, lines 1-19). Preferably, the anchor should be screwed into the bone, rather than driven with an impact tool to lessen the chance of fracturing the bone (column 7, lines 40-52). Where anchor is a screw, preferably an indentation in the shape of a polygon recess to receive an allen wrench is located in marker 12. The use of an allen wrench is due to the increased symmetrical integrity provided over the use of the cross shaped receptor site for a Phillips screw driver or a single groove receptor site for a standard screw driver (column 7, lines 53-61). However, if this symmetry was not important, it would be obvious to use one of these other screwdriver

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shapes. While Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. A “funnel configuration” is used to access precisely the center point of the landmark with a point. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a funnel configuration, as taught by Vilsmeier, in the fiducial system of Allen because Allen states that it is very important to locate the exact center of the marker (column 6, lines 61-68). Vilsmeier states that the funnel configuration allows the surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47).

As a teaching reference, Kraus teaches a bone screw with a substantially spherical head portion and a bone screw shaft. The head is provided with an inlet for engagement with an allen wrench type screwdriver. At the base of the inlet is provided a conical receptacle that provides a point located at the center of the circular head portion when viewed in the axial direction. Kraus teaches a apparatus that incorporates the structural limitations necessary to combine Allen with Vilsmeier. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use Kraus as a teaching reference to incorporate the center point localization of a spherical marker head, as taught by Vilsmeier, while also allowing an allen wrench to fix the screw into the bone, as taught by Allen.

However, none of these references teach a protective cap.

Gordon teaches a cover for orthopedic devices that protrude from a patient's body (see Figure 11). The external housing (see Figures 9-10), which has a disk-like cap and is sized and shaped to fit over a proximal portion of the sidewalls shown in Figures 2-6, has smooth surfaces to avoid and minimize any trauma to surrounding body tissue (see Abstract). Figure 8 illustrates how the proximal end of the medical device is engaged by the cover. Figure 10 illustrates a cover that incorporates a disc-like base and circumferential peripheral cylindrical sidewalls. In Figures 2-6, a slot is shown that extends from the orifice and continues upward, finally circling outward where the sidewall meets the top. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a cover, as taught by Gordon, to a protruding medical device, such as the marker taught by Franklin, in order to avoid and minimize any trauma to surrounding body tissue (see Abstract) if the device is impacted by an external force.

Regarding claim 52, the protective cap described by Gordon is in contact with the surface of the patient, as can be seen in Figure 11. Therefore, it is configured to be adhered to this surface if an adhesive were applied.

Regarding claim 53, the protective cap described by Gordon covers the entirety of the medical device that is external to the patient surface, thereby including the shaft.

Claims 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Allen** in view of **Vilsmeier** and **Kraus**, further in view of **McCroory** et al. (US Patent No. 6,333,971). Allen in view of Vilsmeier and Kraus is described above. Kraus teaches a

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plug to be placed in the divot. However, these bone screw portions do not provide an unthreaded portion. McCrory provides a base portion of an imageable fiducial marker assembly having both a threaded portion and an unthreaded portion. The threaded portion **32**, as illustrated in Figure 2A and 2B, has a small maximum diameter than that of the unthreaded portion, providing for a depth stop. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a narrower threaded portion to separate the fiducial marker from the surface of the patient's skull/bone.

### ***Allowable Subject Matter***

Claims 23-25, 52, 65-66, 76-77, 101-103 and 106 are allowed.

Claims 23, 25, 52 and 76 are allowable over the prior art of record because of the structural limitations of the protective collar.

Claims 65 and 101 are allowable over the prior art of record because of the limitations of the collar, specifically the radial and peripheral slots and the method steps of the fiducial passing through the slots.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/  
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Unit 3737

JMK